



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 12, 2017

Dennis P. Phillion, Ph.D.
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800 North Lindbergh Blvd.
St. Louis, MO 63167

Subject: Application to Amend the Registration of MON 89034 x MIR162 Seed Blend
EPA Registration Number: 524-626
Submission Date: May 23, 2017
OPP Decision Number: 533311

Dear Dr. Phillion:

The amendment referenced above, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable only as an extension to the current unconditionally registered, time-limited registration and provided that you comply with the updated terms and conditions as described in this letter.

1. The subject registration will automatically expire on midnight on November 30, 2029.
2. The subject registration will be limited to a seed blend of MON 89034 field corn [*Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins] and MIR 162 [*Bacillus thuringiensis* Vip3Aa20 protein] and the genetic material necessary for their production [vectors PV-ZMIR245 and pNOV1300] in MON 89034 x MIR 162 corn [OECD Unique Identifier: MON-89034-3 x SYN-IR162-4] seed blended with not less than 5% non-Bt corn seed.
3. Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
4. This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
5. Submit or cite all data required to support MON 89034 within the timeframes required by the terms and conditions of EPA Registration Number 524-575.
6. Monsanto must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

- Requirements relating to creation of a non-Bt corn and/or non-lepidopteran resistant Bt corn refuge in cotton growing regions in conjunction with the planting of any acreage of MON 89034 x MIR162 Seed Blend field corn.
- Requirements for Monsanto to prepare and require MON 89034 x MIR162 Seed Blend users to sign “grower agreements,” that impose binding contractual obligations on the grower to comply with the refuge requirements.
- Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
- Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers’ compliance with IRM requirements.
- Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1A.105, Cry2Ab2, and Vip3Aa20 proteins in the target insects.
- Requirements for Monsanto to develop, and if triggered, to implement a “remedial action plan,” that contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- Requirements for Monsanto, to submit reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program upon request of the Agency, within 3 months of the request.
- Requirements for Monsanto, on or before August 31st of each year, to submit reports on resistance monitoring.

a) Refuge Requirements for MON 89034 x MIR 162 Seed Blend Field Corn

The following information must be included on the product bag or bag-tag as sold per respective region and in the Grower Guide:

1) Corn-Belt Refuge Requirements

There are no requirements for a separate structured refuge for MON 89034 x MIR162 Seed Blend corn when planted in the U.S. Corn Belt. The refuge seed of MON 89034 x MIR162 Seed Blend corn is contained in the bag resulting in a refuge configuration that is interspersed within the field.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 x MIR162 Seed Blend field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-

lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field. External refuges must be planted within ½ mile.

When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.

Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Monsanto to help these growers meet the refuge requirements across their farming operations.

For the sole purpose of manufacturing and small scale research trials for observation, these refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant- incorporated protectant (PIP) active ingredient per registrant per year.

b) Grower Agreements for MON 89034 x MIR162 Seed Blend

- 1) Persons purchasing MON 89034 x MIR162 Seed Blend must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing MON 89034 x MIR162 Seed Blend corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Monsanto must continue to use its current grower agreement for MON 89034 x MIR162 Seed Blend corn. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents

referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

5) Monsanto shall maintain records of all MON 89034 x MIR162 Seed Blend grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

6) Monsanto shall make available to the Agency upon request records of the number of units of MON 89034 x MIR 162 Seed Blend corn seed sold, or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season, within three months of the request.

7) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and Compliance Monitoring Programs for MON 89034 x MIR162 Seed Blend

1. Monsanto must implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 89034 x MIR162 Seed Blend corn users the importance of complying with the IRM program, as well as seed blend product performance expectation and guidance to growers on actions to take when unexpected damage occurs. The program shall include information encouraging MON 89034 x MIR162 Seed Blend corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 x MIR162 Seed Blend corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. The program shall involve at least one written communication annually to each MON 89034 x MIR162 Seed Blend corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge in cotton-growing regions. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2. Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3. Upon EPA request, Monsanto shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Monsanto is required to submit reports within three months of the Agency's request. The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4. Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 x MIR162 Seed Blend corn are compliant with the requirement of a 20% refuge for lepidopteran pests in cotton growing areas, and that takes

such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Monsanto's Bt corn products. Monsanto shall coordinate with other Bt corn registrants in improving its compliance assurance program and integrate this registration into the current compliance assurance program used for its other Bt corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5. Monsanto must continue to maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access the next year to Monsanto's Bt corn products for which the grower is required to plant a separate structured refuge. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Bt corn.

6. The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers MON 89034 x MIR162 Seed Blend corn. The survey shall be conducted in odd-numbered years beginning in 2017 and shall include growers who plant 100 or more acres of corn in the Southern U.S. corn-cotton areas. Monsanto may collaborate with other registrants of Bt corn [for example, through the industry working group the Agricultural Biotechnology Stewardship Technical Committee (ABSTC)] to conduct the survey.

In the U.S. Corn Belt, no anonymous grower survey is required for MON 89034 x MIR162 Seed Blend corn if Monsanto can demonstrate that the industry-wide adoption of integrated refuge products (i.e., refuge seed blends) is equal to or greater than 70% of Bt corn acres in the Corn Belt. If industry-wide adoption of integrated refuge products (i.e., refuge seed blends) falls below 70% of Bt corn acres in the Corn Belt, an anonymous grower survey shall also be conducted in this region during the next growing season using a statistically representative sample of growers who plant 200 or more acres of corn, and grower surveys shall be continued every odd-numbered year until the industry-wide adoption of integrated refuge products (i.e., refuge seed blends) is again equal to or greater than 70% of Bt corn acres in this region. Monsanto may collaborate with other registrants of Bt corn (for example, through the industry working group the ABSTC) to compile the integrated refuge adoption data and to conduct the surveys.

Alternatively, if Monsanto is not a participant of an industry working group (e.g., the ABSTC) and Monsanto's sales of integrated refuge products are equal to or greater than 70% of Monsanto's total Bt corn sales in the prior year, then no anonymous grower survey is required in the U.S. Corn Belt. If Monsanto's sales of integrated refuge products fall below 70% of Monsanto's total Bt corn sales, an anonymous grower survey shall also be conducted in this region during the next growing season using a statistically representative sample of growers who plant 200 or more acres of corn, and grower surveys shall be continued every odd-numbered year until sales of integrated refuge products (i.e., refuge seed blends) are again equal to or greater than 70% of Monsanto's total Bt corn sales in this region.

- A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for Bt corn.

7. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9. In years in which the survey is conducted, Monsanto shall provide a final written summary of the results of the survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of the following year. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10. Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with EPA prior to adopting any changes.

11. Monsanto shall continue to conduct and enhance an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with MON 89034 x MIR162 Seed Blend corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12. Monsanto shall implement a program for investigating legitimate tips and complaints that MON 89034 x MIR162 Seed Blend corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its phased compliance approach.

13. If a grower, who purchases MON 89034 x MIR162 Seed Blend corn for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14. Annually, by January 31st each year, Monsanto must provide a report to EPA summarizing the MON 89034 x MIR162 Seed Blend compliance assurance program activities and results for the prior year and plans for the MON 89034 x MIR162 Seed Blend compliance assurance program for the current year. Within one month of submitting this report to EPA, Monsanto shall meet with EPA to discuss its findings. The report must inform EPA of the number of growers deemed ineligible to purchase Bt corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15. Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16. Monsanto shall revise and expand its existing Compliance Assurance Program to include the following elements. Monsanto may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

17. Monsanto will enhance the refuge education program throughout the seed delivery channel:

- Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- Implement a “bag tag” that will be attached to all bags of MON 89034 x MIR162 Seed Blend seed sold and delivered. The purpose of this bag tag is to remind growers that MON 89034 x MIR162 Seed Blend seed products require a separate 20% lepidopteran refuge in cotton growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

18. Monsanto will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- Use Bt corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where MON 89034 x MIR162 Seed Blend is used.

19. Monsanto will use its available MON 89034 x MIR162 Seed Blend sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- Identify for potential on-farm assessment growers whose sales information indicates they have purchased MON 89034 x MIR162 Seed Blend corn product but may have purchased little or no the registrant, licensee, or affiliated company.

20. Monsanto will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

21. Monsanto will annually refine the on-farm assessment program for the MON 89034 x MIR162 Seed Blend product to reflect the adoption rate and level of refuge compliance for the product.

22. Monsanto will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Monsanto, seed supplier, or third party assessor, after completing the assessment process;
- Monsanto will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- A grower found with a second incident of significant non-compliance with refuge requirements for the Bt corn product within a five-year period will be denied access to Monsanto’s Bt corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Bt corn.

d) Insect Resistance Monitoring and Remedial Action Plan for MON 89034 x MIR162 Seed Blend

The Agency is imposing the following conditions for the Cry1A.105, Cry2Ab2, and Vip3Aa20 toxins expressed in MON 89034 x MIR162 Seed Blend corn:

- Monsanto must monitor for resistance to Cry1A.105, Cry2Ab2, and Vip3Aa20 expressed in MON 89034 x MIR162 Seed Blend corn.
- The resistance monitoring program must include the following two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than-expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Annually, Monsanto shall sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 x MIR162 Seed Blend and/or changes in resistance-allele frequency in response to the use of MON 89034 x MIR162 Seed Blend and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 x MIR162 Seed Blend must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034 x MIR162 Seed Blend. The Agency shall be consulted prior to the implementation of such modifications.

Monsanto will report to the Agency by August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105, Cry2Ab2, and/or Vip3Aa20 proteins in

bioassays shall be investigated as soon as possible to understand any field relevance of such a finding.

Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 x MIR162 Seed Blend under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - Determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - Estimating the resistance-allele frequency in the original population;
 - Determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - Determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.
 - Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the product label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives. If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- The corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- The seed used had the proper percentage of corn expressing *Bt* protein;
- The relevant plant tissues are expressing the expected level of *Bt* protein; and it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 x MIR162 Seed Blend in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 x MIR162 Seed Blend fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 x MIR162 Seed Blend crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.
- In standardized laboratory bioassays, the LC50 exceeds the upper limit of the 95% confidence interval of the LC50 for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan;
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, for the duration of the unconditional registration.

e) Annual Reporting Requirements for MON 89034 x MIR162 Seed Blend Corn

- 1) Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey results (only for years in which the survey was conducted) and on-farm assessment results for the prior year plans for the compliance assurance program for the current year, on or before January 31st of each year.
- 2) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st each year.

f) Refuge Assurance Program for MON 89034 x MIR162 Seed Blend Corn

Monsanto and Monsanto's seed company licensees must continue to implement a blended seed refuge assurance program designed to ensure MON 89034 x MIR162 Seed Blend corn products are formulated with the appropriate rate of refuge seeds.

The program must include the following four elements:

- 1) Trait purity check on seed lots prior to blending (Monsanto and Monsanto Licensees)
 - 2) Standard Operating Procedures for the blending process;
 - 3) Calibration of blending equipment; and
 - 4) Records and data retention records for seed blend products.
- Calibration records – Monsanto and Monsanto's Licensees will retain documentation for three (3) years on the equipment calibration including the procedure, when it was conducted and the results.
 - Blend proportion records (weight and kernel based) – Monsanto and Monsanto Licensees will retain documentation for three (3) years on the kernel per pound data of the components, the calculations to

determine the proportions based on weight and the actual weights that are blended together to make up an MON 89034 x MIR162 Seed Blend corn product by seed lot. All records must be maintained at the Monsanto or Monsanto Licensees seed blending facility and must be available for the EPA review upon request.

Should Monsanto or Monsanto's licensees be notified by the USDA/AMS or State Seed Control Officials that your seed blend products have been found to have a lower percentage of the refuge component than is represented on the label, they must notify EPA within 30 days. This would constitute information reportable under FIFRA section 6(a)(2).

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped copy of the approved label for this product is enclosed for your records.

If you have any questions, please contact Matt Weiner by phone at (703) 347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,



Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant Label

MON 89034 × MIR162 Seed Blend

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4)

(Alternate Brand Name: Trecepta™ RIB Complete® corn blend)‡

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in MON 89034 × MIR162 corn ≤0.0059%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in MON 89034 × MIR162 corn ≤0.0043%*

Bacillus thuringiensis Vip3Aa20 protein and the genetic material necessary for its production (vector pNOV1300) in MON 89034 × MIR162 corn ≤0.015%*

Other Ingredients:

Phosphomannose isomerase (PMI) marker protein and the genetic material necessary (vector pNOV1300) for its production in MON 89034 × MIR162 corn ≤0.00068%*

*Percentage (wt/wt) on a dry weight basis for whole plant (forage) of MON 89034 × MIR162 plants.

The MON 89034 × MIR162 seed with this refuge configuration contains 95% MON 89034 × MIR162 mixed with 5% non-*Bt* corn within a single lot of seed

‡ Trecepta™ RIB Complete® corn blend with this refuge configuration contains 95% of the plant-incorporated protectant MON 89034 × MIR162 mixed with 5% non-*Bt* corn within a single lot of seed

KEEP OUT OF REACH OF CHILDREN

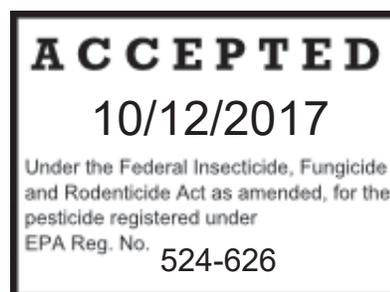
Caution

NET CONTENTS _____

EPA Registration No. 524-626

EPA Establishment No. 524-MO-002

Monsanto Company
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St Louis, MO 63167



DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the grower guide. MON 89034 × MIR162 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers and corn earworm.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

Refuge Requirements

A refuge must consist of corn hybrids that do not contain Bt technologies for the control of corn borers and corn earworm. This product achieves the required refuge as the refuge is interspersed within the field and occurs only by planting a licensed seed-mixture containing MON 89034 × MIR162 or MON 89034 × MIR162 stacked with other non-PIP technologies, with a minimum of 5% non-PIP seed. This refuge configuration complies with refuge requirements only in the U.S. Corn Belt.

The sufficiency of this refuge configuration is defined by geography, and ultimately is based on insect presence and species. **The seed mix refuge option for MON 89034 × MIR162 complies with refuge requirements only in the U.S. Corn Belt.**

The 95/5% MON 89034 × MIR162 seed mix product may be planted in cotton growing areas; however, planting the 95/5% MON 89034 × MIR162 seed mix in cotton growing areas still requires planting an additional structured refuge of at least 20% corn, which is not a Lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control Lepidopteran stalk-boring and other pests. **The interspersed refuge option for MON 89034 × MIR162 does not alone comply with refuge requirements in cotton growing areas.**

Structured refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field. External refuges must be planted within ½ mile. When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City,

Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The seed mix (interspersed) refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × MIR162 and MON 89034 × MIR162 stacks with non-PIP corn.

The field containing an interspersed refuge may be treated with labeled insecticides to control additional corn pests, including larval or adult Lepidopteran pests, because both the MON 89034 × MIR162 and refuge are treated in the same manner. Insecticide treatments for control of pests listed on this label may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial Bt insecticides must not be applied to the field containing a seed mix interspersed refuge.

For the sole purpose of manufacturing and small scale research trials for observation, these refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

Corn Insects Controlled or Suppressed

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>
Beet armyworm	<i>Spodoptera exigua</i>
True armyworm	<i>Pseudeletia unipuncta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western bean cutworm	<i>Striacosta albicosta</i>
Lesser cornstalk borer	<i>Elasmopalpus lignosellus</i>
Dingy Cutworm	<i>Feltia jaculifera</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant incorporated protectant must be accompanied by a grower guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × MIR162 seed blend is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents that can be found at <http://www.monsantotechnology.com>